N THE UNITED STATES PATENT AND TRADEMARK OFFICE Atty. Docket: MOTOMIYA = 1Application of: Conf. No.: 6615 Yoshihiro MOTOMIYA et al Art Unit: 1632 Appln. No.: 10/516,688 Examiner: Filing Date: June 6, 2003 Washington, D.C. August 8, 2005 For: AGENT FOR TREATMENT OF METABOLIC BONE DISEASE

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents U.S. Patent and Trademark Office Randolph Building, Mail Stop Amendment 401 Dulany Street Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

- [X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed before the mailing date of a first office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 CFR §1.114.
- [X] 2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published U.S. application(s),

In re Appln. No. 10/516,688

which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached.

- [X] 3. Documents \underline{AF} and \underline{AH} are not in the English language. In accordance with 37 CFR §1.98(a)(3), Applicant states:
 - [X] An English translation of each document AF and AH (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.
- [X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- [] 5. Other information being provided for the examiner's consideration follows:

International Search Report

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

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Substitute for form 1449A/PTO				Complete if Known			
				Application Number	10/516,688		
INFO	RMATION D	ISC	LOSURE	Filing Date	June 6, 2003	1010	1
STATEMENT BY APPLICANT (use as many sheets as necessary)			PLICANT	First Named Inventor	Yoshihiro, MOTO	MIYA et al	1
				Group Art Unit	1632	AUG 0 8 2005	Ó
			ecessary)	Examiner Name		£	G
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FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Number Country Code ³ Number ⁴ Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵	
	AA	EP 0 499 242 A1	08-19-1992	TAKEDA CHEMICAL INDUSTRIES, LTD.			

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS		
Examiner C	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, cite magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or count published			
	AB	IMAZEKI, et al, ""Rapidly progressive renal failure model rat induced by adenine diet". J. Am. Soc. Nephrol. (2001). 12: A4267.	-	
	AC	KOEDA, et al, "Early changes of proximal tubles in the kidney of adenine-ingesting rats, with special reference to biochemical and electron microscopic studies". Japanese Journal of Nephrology. (1988). 30(3):239-246.		
	AD	MORIGUCHI, et al, "Rapidly progressive secondary hyperparathyroidism due too renal failure in rats induced by adenine diet". J. Am. Soc. Nephrol. (2001) 12: A4301.		
	AE	MUNDY, G.R., "Factors which stimulate bone growth in vivo". Growth Regulation. (1993). 3:124-128.		
	AF	OKADA, et al, "Effect of rHuEPO on bone mineral density (BMD)". Proceedings of the 9 th Congress on Kidney and Erythropoietin Study. (October 28, 2000). Tokyo. pp. 37-41.	Abs	
	AG	YOKAZAWA, et al, "Animal model of adenine-induced chronic renal failure in rats". Nephron. (1986). 44:230-234.		
	АН	YOKOZAWA, et al, "Adenine-induced hyperuricemia and renal damage in rats". Nippon Nogeikagaku Kaishi (1982). 56(8):655-663.	Abs.	

Examiner	Date		
Signature	Considered		

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as Indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language Translation is attached.